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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Kohn, et al.
Serial No.:	08/225,478
Filed:	April 8, 1994
For:	Gene Therapy by Administration of Genetically Engineered $CD34^+$ Cells Obtained from Cord Blood
Group:	1632
Examiner:	Campell

Assistant Commissioner of Patents
Washington, DC 20231

Sir:

DECLARATION UNDER 37 C.F.R. 1.131

We, Donald B. Kohn, R. Michael Blaese, Craig A. Mullen, and Robert C. Moen, hereby declare as follows:

1. We are the inventors of the claimed subject matter of the above-identified application.

2. We are aware of a rejection of the pending Claims 1-15 and 21-26 of the above-identified application under 35 U.S.C. 103(a) as being unpatentable over Anderson, et al., 1992, Moritz, et al., J. Exp. Med., Vol. 178, pgs. 529-536 (August 1993), and Kohn, et al., 1992, in view of Boyse, et al., 1993, or Moore, et al., Journal of Hematotherapy, Vol. 2, pgs. 221-224 (Summer 1993).

3. Exhibit 1, attached hereto, consists of laboratory notebook pages describing work done by us or others acting on our behalf. Such work was done in the United States.

4. As described in Exhibit 1, two infants that were diagnosed with severe combined immune deficiency, or SCID, were given autologous cord blood CD34+ cells that had been transduced with a retroviral vector named LASN, which includes cDNA encoding human ADA.

5. More particularly, cord blood was obtained from each infant at birth, and CD34+ cells were isolated from other blood cells by contacting the cord blood cells with an antibody known as antibody 12.8, which recognizes CD34.

6. The isolated autologous CD34+ cells then were transduced with the retroviral vector LASN.

7. The transduced autologous CD34+ cells then were administered to each infant.

8. Such work also is described in Example 2 of the above-identified application at Pages 21 and 22, wherein CD34+ cells obtained from the cord blood of Patient 1 and Patient 2 were transduced with the retroviral vector LASN, followed by the administration of the transduced autologous CD34+ cells to Patient 1 and Patient 2.

9. Such work was done prior to the summer of 1993, and thus was done prior to the publication of the Moritz and Moore references.

10. We hereby declare that all statements made herein are true and that all statements made on information and belief are believed to be true, and further, that any willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Date: 1/24/95

Donald B. Kohn

R. Michael Blaese

Craig A. Mullen

Robert C. Moen